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SB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/619,901 07/19/00 BOTICH

M 1032-P00101U

000110 QM32/0709
DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA PA 19103-2307

EXAMINER

SERGE, C.

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

07/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/619,901

Applicant(s)

BOTICH ET AL.

Examiner

Catherine Serke

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Ridderheim et al.

Ridderheim discloses a medical device having a needle (12) operable between a projected position and a retracted position (see figures 9a-9e), a housing (10) having a fluid cavity, a dead space area (distal tapered portion of fluid cavity, see figure 2), a plunger (14) with a cavity, a piston tip (see distal end of the plunger 14, figure 2), a biasing element (56) and a needle hub (70) with a needle retainer/connector (64). As shown in figure 2, the dead-space area is part of the housing fluid cavity. The needle retainer has a frangible connection (78) that is fractured during forward displacement of the plunger.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Villen Pascual.

Villen Pascual discloses a medical device having a needle (2) operable between a projected position and a retracted position (see figures 1-2), a housing (1) having a fluid cavity, a dead space area (distal portion of fluid cavity, see figure 1), a plunger (11) with a cavity (17), a piston tip (15), a biasing element (9) and a needle hub (4) with a needle retainer/connector (6). As shown in figure 1, the dead-space area is part of the housing

fluid cavity. The needle retainer has a frangible connection (hinge) that is fractured during forward displacement of the plunger.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaarde.

Gaarde discloses a medical device having a needle (1) operable between a projected position and a retracted position (see figures 1-2), a housing (5) having a fluid cavity, a dead space area (distal portion of fluid cavity, see figure 1), a plunger (7) with a cavity (9), a piston tip (10), a biasing element (2) and a needle hub (3) with a needle retainer/connector (6). As shown in figure 1, the dead-space area is part of the housing fluid cavity. The needle retainer has a frangible connection (small aperture) that is fractured during forward displacement of the plunger.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 8-9 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 10 of prior U.S. Patent No. 6,096,005 and claims 20,23 and 24 of prior U.S. Patent No. 6,096,005. This is a double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on 703-305-0154. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.



Catherine Serke
June 27, 2001


Sharon Kennedy
Sharon Kennedy
Primary Examiner